

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Music Therapy with Nature Sounds on Anxiety and Pain of Change Dressings For Burn Patients

Protocol summary

Study aim

Determining the effect of music therapy with the sounds of nature on anxiety and pain during dressing changes in burn patients

Design

Clinical trial with a control group, with parallel groups, single-blind, randomized on 86 burn patients Using the simple random method and using the table of random numbers

Settings and conduct

This research is an interventional study that will be conducted in Arak. After selecting the research samples, the patients will be divided into test and control groups randomly. Then, the patients of each group complete the demographic information, the pain intensity and Spielberger questionnaire. Then i before the start of the intervention, the level of pain and anxiety of the patient is measured while changing the patient's dressing, and on the second day of the intervention, the level of pain and anxiety of the patient is measured while changing the dressing. The intervention is carried out in such a way that the MP3 Player and headphones are used for two consecutive days during the dressing change. Start 15 minutes before changing the dressing and listen to the sounds of nature for 30 minutes respectively. they listen In addition, each one is presented for 5 minutes and this process is repeated for 30 minutes. Using the same method before the intervention and immediately after the intervention, the amount of basic pain and anxiety is measured.

Participants/Inclusion and exclusion criteria

Age from 18 to 65 years, patient's ability to answer the questions (in terms of physical and mental condition), written consent to participate in the study

Intervention groups

The intervention in this study includes playing music with the sounds of nature for 30 minutes while changing the patient's dressing.

Main outcome variables

Pain, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033751N5**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

rezvan ghafarzadegan

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3426 2226

Email address

rghafarzadegan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Music Therapy with Nature Sounds on Anxiety and Pain of Change Dressings For Burn Patients

Public title

The Effect of Music Therapy on Anxiety and Pain in Burn Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 65 years, the patient's ability to answer questions (in terms of physical and mental condition), having a stable and stable hemodynamic status, 2nd or 2nd and 3rd degree burns together with a range of 15 to 60% who have passed the resuscitation or urgent stage, written consent to participate in the study

Exclusion criteria:

patient's neurological and mental disease addiction to cigarettes and other narcotic drugs Having comorbidity

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the research samples, the patients will be divided into intervention and control groups using simple random method and random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the person who analyzes the study data after entering the data into the statistical software is not aware of the allocation of the study groups and the type of intervention allocated and does not know which individual in the test group each of the data is related to. or control.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Khomein Faculty of Medical Sciences

Street address

No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences Khomein, Quds Boulevard

City

Khomein

Province

Markazi

Postal code

3881857573

Approval date

2023-07-10, 1402/04/19

Ethics committee reference number

IR.KHOMEIN.REC.1402.002

Health conditions studied**1****Description of health condition studied**

burn

ICD-10 code

M61.3

ICD-10 code description

Calcification and ossification of muscles associated with burns

Primary outcomes**1****Description**

Pain score according to pain intensity questionnaire(primary outcome)

Timepoint

before the beginning of the stages and on the second day after the intervention

Method of measurement

Pain measurement questionnaire

2**Description**

Anxiety score according to the Spielberger anxiety questionnaire(secondry outcome)

Timepoint

before the beginning of the stages and on the second day after the intervention

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:"Music therapy is performed using MP3 Player and headphones two days in a row at the time of dressing change, and they start 15 minutes before dressing change and listen to the sounds of nature for 30 minutes, which are birds singing, water and rain respectively. In addition, each type of music is presented for 5 minutes and this process is repeated for 30 minutes.

Category

Rehabilitation

2

Description

"Control group:" Dressing according to the doctor's order and in accordance with the usual treatment and without performing music therapy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirulmomenin Arak Hospital

Full name of responsible person

rezvan ghafarzadegan

Street address

No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard

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3881743364

Phone

+98 86 4622 1534

Email

rghafarzadegan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein Faculty of Medical Sciences

Full name of responsible person

reza beiranvand

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No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences,Quds Boulevard

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Email

beiranvandreza@ymail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khomein Faculty of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Khomein Faculty of Medical Sciences

Full name of responsible person

rezvan ghafarzadegan

Position

academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khomein Faculty of Medical Sciences

Full name of responsible person

reza beiranvand

Position

academic instructor

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying individuals

When the data will become available and for how long

1403

To whom data/document is available

All researchers

Under which criteria data/document could be used

To conduct related research

From where data/document is obtainable

No. 20, Building of the Vice-Chancellor of the Faculty of Medical Sciences, Quds Boulevard, Khomein, Mr. Reza Biranvand, phone number: 08646221534, fax: 08646224142

What processes are involved for a request to access data/document

Submitting a written request via fax to receive documents to the Vice-Chancellor of Education and Research of Khomein Faculty of Medical Sciences and receiving information related to the research after a maximum of one month.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Khomein Faculty of Medical Sciences

Full name of responsible person

rezvan ghafarzadegan

Position

academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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